ENVIRONMENTAL PROTECTION AGENCY

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10011-21-OW

RIN 2040-AF28

Drinking Water: Final Action on Perchlorate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: The Environmental Protection Agency (EPA) is announcing its withdrawal of the 2011 determination to regulate perchlorate in accordance with the Safe Drinking Water Act, (SDWA). On February 11, 2011, the EPA published a Federal Register document in which the Agency determined that perchlorate met the SDWA's criteria for regulating a contaminant. On June 26, 2019, the EPA published a proposed national primary drinking water regulation (NPDWR) for perchlorate and requested public comments on multiple alternative actions, including the alternative of withdrawing the 2011 regulatory determination for perchlorate. The EPA received approximately 1,500 comments on the proposed rulemaking. The EPA has considered these public comments and based on the best available information the Agency is withdrawing the 2011 regulatory determination and is making a final determination not to regulate perchlorate. The EPA has determined that perchlorate does not occur "with a frequency and at levels of public health concern" within the meaning of the SDWA. In addition, in the judgment of the EPA Administrator, regulation of perchlorate does not present a "meaningful opportunity for health risk reduction for persons served by public water systems." Accordingly,

the EPA is withdrawing its 2011 determination and is making a final determination not to regulate perchlorate, and therefore will not issue a NPDWR for perchlorate at this time.

DATES: For purposes of judicial review, the regulatory determination in this document is issued as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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I. General Information

A. Does This Action Apply to Me?

This action will not impose any requirements on anyone. Instead, this action notifies interested parties of the EPA's withdrawal of the 2011 regulatory determination for perchlorate and the final regulatory determination not to regulate perchlorate. Section IV of this document provides a summary of the key comments received on the June 26, 2019 (84 FR 30524) proposed NPDWR for perchlorate (referred to hereinafter as "the 2019 proposal").

B. How can I get Copies of this Document and other Related Information?

The EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2018-0780. Publicly available docket materials are available electronically at https://www.regulations.gov/docket?D=EPA-HQ-OW-2018-0780.

II. Background

A. What is Perchlorate?

Perchlorate is a negatively charged inorganic ion that is composed of one chlorine atom bound to four oxygen atoms (ClO₄-), which is highly stable and mobile in the aqueous environment. Perchlorate comes from both natural and manmade sources. It is formed naturally via atmospheric processes and can be found within mineral deposits in certain geographical areas. It is also produced in the United States by industrial processes, and the most commonly produced compounds include ammonium perchlorate and potassium perchlorate used primarily as oxidizers in solid fuels to power rockets, missiles, and fireworks. Perchlorate can also result from the degradation of hypochlorite solutions used for water disinfection. The degradation into perchlorate occurs when hypochlorite solutions are improperly stored and handled. For the general population, most perchlorate exposure is through the ingestion of contaminated food or drinking water. Above certain levels, perchlorate can prevent the thyroid gland from getting enough iodine, which can affect thyroid hormone production. The consequences of insufficient thyroid hormone levels during human growth and development are well

known. For pregnant women with low iodine levels, sufficient changes in thyroid hormone levels may cause changes in the child's brain development. In a 2005 report entitled "Health Implications of Perchlorate Ingestion", the National Research Council stated that: "fetuses and preterm newborns constitute the most sensitive populations although infants and developing children are also considered sensitive populations" (NRC, 2005). The existence of a quantifiable relationship between thyroid hormone changes and neurodevelopmental outcomes has strong support from the literature on the subject; however, not every study identifies an association between maternal thyroid hormone levels and the neurodevelopmental outcomes, and the state of the science on this relationship is constantly evolving.

B. What is the Purpose of this Action?

The purpose of this action is to publish the EPA's notice to withdraw the 2011 regulatory determination, one of the alternative options in the 2019 proposal, and to issue a final determination not to regulate perchlorate in drinking water. This document presents the EPA's basis for this withdrawal and final regulatory determination, and the EPA's response to key issues raised by commenters in response to the 2019 proposal.

C. What is the EPA's statutory authority for this action?

The SDWA sets forth three criteria that must be met for the EPA to issue a maximum contaminant level goal (MCLG) and promulgate a national primary drinking water regulation (NPDWR). Specifically, the Administrator must determine that (1) "the contaminant may have

an adverse effect on the health of persons"; (2) "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern"; and (3) "in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems" (SDWA 1412(b)(1)(A)).

SDWA 1412(b)(1)(B) sets out the process for the EPA to establish drinking water standards for an unregulated contaminant. As explained in more detail below, in 2011, the EPA issued a determination that perchlorate met the three statutory criteria outlined above and therefore should be regulated. Under the statute, a determination to regulate triggers a duty for the EPA to issue a proposed drinking water standard within two years and a final rule 18 months later (with the possibility of a 3 month extension). SDWA 1412(b)(1)(E). The EPA subsequently published a proposed drinking water standard for perchlorate, and alternatives including the withdrawal of the 2011 regulatory determination, in 2019. The promulgation of a final drinking water standard would, when effective, require monitoring of public water supplies for the contaminant and treatment as necessary to meet the regulatory standard.

The EPA has determined, based on reviewing data and analysis obtained since the issuance of the 2011 regulatory determination, that perchlorate does not meet the statutorily-prescribed criteria for regulation. As described in Sections III & VI of the 2019 proposal, the data and analysis in the record indicate that perchlorate does not occur in public water systems with a frequency and at levels of public health concern. Specifically, the peer-reviewed health

effects analysis indicates that the estimated concentrations of perchlorate that may represent levels of public health concern (i.e., the proposed MCLG levels, 18-90 μg/L) is higher than the concentration considered in issuance of the 2011 regulatory determination (1-47 µg/L) (USEPA, 2019a). In addition, based on a re-evaluation of the nationally representative First Unregulated Contaminant Monitoring Rule (UCMR 1) data, the updated occurrence analysis shows that the frequency of occurrence of perchlorate in public water systems at levels exceeding any of the alternative proposed MCLGs (18 μ g/L – 90 μ g/L) is significantly lower (0.03% - 0.002%) than the frequency considered in the analysis for the 2011 regulatory determination (4% - 0.39%)(USEPA, 2019b). The EPA estimates that, even at the most stringent regulatory level considered in the 2019 proposal (18 μ g/L), not more than 15 systems (0.03% of all water systems in the U.S. serving approximately 620,000 people) would need to take action to reduce levels of perchlorate. Based on this information, the EPA determines that perchlorate does not occur in public water systems "with a frequency and at levels of public health concern" and thus does not meet the second criterion of the three required for regulation under the SDWA. In addition, while the third criterion is "in the sole judgment of the Administrator," the small number of water systems with perchlorate levels greater than identified thresholds, and the correspondingly small population served, provides ample support for the EPA's conclusion that the regulation of perchlorate does not present a "meaningful opportunity for health risk reduction for persons served by public water systems," within the meaning of 1412(b)(1)(A)(iii). Accordingly, because perchlorate no

longer meets the statutory criteria for regulation, the EPA does not have the authority to issue a MCLG or promulgate a NPDWR for perchlorate.

While the EPA has not previously withdrawn a regulatory determination, the decision is supported by the legislative history underlying the 1996 amendments to the SDWA, which repealed the statutory requirement for the EPA to regulate an additional 25 contaminants every 3 years and replaced it with the current requirement for the EPA to determine whether regulation is warranted for five contaminants every five years. In describing the need for such amendment, the legislative history points to the view expressed at the Committee Hearing that "the current law is a one-size-fits-all program. It forces our water quality experts to spend scarce resources searching for dangers that often do not exist rather than identifying and removing real health risks from our drinking water" (S. Rep. 104-169 (1995) at 12). This amendment reflected Congress' clear intent that the EPA prioritize actual health risks in determining whether to regulate any particular contaminant. See id at 12 (noting that the amendment "repeals the requirement that the EPA regulate an additional 25 contaminants every 3 years replacing it with a new selection process that gives the EPA the discretion to identify contaminants that warrant regulation in the future").

The EPA's decision to withdraw the regulatory determination is also consistent with Congress' direction to prioritize SDWA decisions based on the best available public health information. *See* 1412(b)(1)(B)(ii)(II) (findings supporting a determination to regulate "shall be based on the best available public health information"); 1412(b)(2)(A) (requiring that the EPA

use "the best available, peer-reviewed science and supporting studies..." in carrying out any actions under this section). Although the EPA determined in 2011 that perchlorate met the criteria for regulation, new data and analysis developed by the Agency as part of the 2019 proposal demonstrate that the occurrence and health effects information used as the basis for the 2011 determination no longer constitute "best available information," are no longer accurate, and no longer support the Agency's prioritization of perchlorate for regulation. Accordingly, not only is the EPA not authorized to issue a MCLG or promulgate a NPDWR for perchlorate, but it would not be in the public interest for the EPA to do so.

The EPA recognizes that the SDWA does not include a provision explicitly authorizing withdrawal of a regulatory determination. However, such authority is inherent in the authority to issue a regulatory determination under 1412(b)(1)(B)(ii)(II), particularly given the requirement that such determination be based on the "best available public health information," as discussed above. Accordingly, the EPA must have the inherent authority to withdraw a regulatory determination if the underlying information changes between regulatory determination and promulgation. In light of Congress's concern that the EPA focus new contaminant regulations on priority health concerns, Congress could not have intended that the EPA's regulatory decision-making be hamstrung by older data when newer, more accurate scientific and public health data are available, especially when those data demonstrate that regulation of a new contaminant would not present a meaningful opportunity for health risk reduction.

Moreover, the EPA notes that the statute specifically provides that a decision not to regulate a contaminant is a final Agency action subject to judicial review. SDWA 1412(b)(1)(B)(ii)(IV). Congress could have – but did not – specify the same with respect to determinations to regulate. Congress also did not explicitly prohibit the EPA from withdrawing or modifying a regulatory determination. Congress' silence with respect to determinations to regulate suggests that Congress intended that such a determination is not itself a final agency action, but rather a preliminary step in a decision-making process culminating in a NPDWR and thus subject to reconsideration based on new data and analysis considered during the 36 month promulgation process specified in the statute. Accordingly, reconsideration of this preliminary finding – and withdrawal of the determination based on subsequent analysis mandated for NPDWR development – is fully consistent with the statutory decision-making framework.

D. Statutory Framework and Perchlorate Regulatory History

Section 1412(b)(1)(B)(i) of the SDWA requires the EPA to publish every five years a Contaminant Candidate List (CCL). The CCL is a list of drinking water contaminants that are known or anticipated to occur in public water systems and are not currently subject to federal drinking water regulations. The EPA uses the CCL to identify priority contaminants for regulatory decision-making and information collection. The placement of a substance on the CCL does not require that it be regulated under the SDWA. Contaminants listed on the CCL may require future regulation under the SDWA. The EPA included perchlorate on the first, second,

and third CCLs published in 1998 (63 FR 10274, March 2, 1998), 2005 (70 FR 9071, February 24, 2005), and 2009 (74 FR 51850, October 8, 2009).

The EPA collects data on the CCL contaminants to better understand their potential health effects and to determine the levels at which they occur in public water systems. SDWA 1412(b)(1)(B)(ii) requires that, every five years, the EPA, after consideration of public comment, issue a determination of whether or not to regulate at least five contaminants on each CCL. For any contaminant that the EPA determines meets the criteria for regulation under SDWA 1412(b)(1)(E), the EPA must propose a NPDWR within two years and promulgate a final regulation within 18 months of the proposal (which may be extended by 9 additional months).

As part of its responsibilities under the SDWA, the EPA implements section 1445(a)(2) ("Monitoring Program for Unregulated Contaminants"). This section requires that once every five years, the EPA issue a list of no more than 30 unregulated contaminants to be monitored by public water systems. This monitoring is implemented through the Unregulated Contaminant Monitoring Rule (UCMR), which collects data from community water systems and non-transient, non-community water systems. The first four UCMRs collected data from a census of large water systems (serving more than 10,000 people) and from a statistically representative sample of small water systems. On September 17, 1999, the EPA published its first UCMR (64 FR 50556), which required all large systems and a representative sample of small systems to monitor for perchlorate and 25 other contaminants (USEPA, 1999). Water system monitoring data for perchlorate were collected from 2001 to 2005.

The EPA and other federal agencies asked the National Research Council (NRC) to evaluate the health implications of perchlorate ingestion. In its 2005 report, the NRC concluded that perchlorate exposure inhibits the transport of iodide¹ into the thyroid by a protein molecule known as the sodium/iodide symporter (NIS), which may lead to decreases in the production of two thyroid hormones, thyroxine (T3) and triiodothyronine (T4), and increases in the production of thyroid-stimulating hormone (TSH) (National Research Council (NRC), 2005). Additionally, the NRC concluded that the most sensitive population to perchlorate exposure are "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" (p. 178). The EPA established a reference dose (RfD) consistent with the NRC's recommended RfD of 0.7 µg/kg/day for perchlorate. The reference dose is an estimate of a human's daily exposure to perchlorate that is likely to be without an appreciable risk of adverse effects. This RfD was based on a study (Greer, Goodman, Pleus, & Greer, 2002) of perchlorate's inhibition of radioactive iodine uptake in healthy adults and the application of an uncertainty factor of 10 for intraspecies variability (USEPA, 2005a).

In October 2008, the EPA published a preliminary regulatory determination not to regulate perchlorate in drinking water and requested public comment (73 FR 60262, October 10, 2008). In that preliminary determination, the EPA found that perchlorate did not occur with a

¹ For the purposes of this document, "iodine" will be used to refer to dietary intake before entering the body. Once in the body, "iodide" will be used to refer to the ionic form.

frequency and at levels of public health concern within the meaning of the SDWA, and that development of a regulation did not present a meaningful opportunity for health risk reduction for persons served by public water systems. In reaching this conclusion, the EPA derived and used a Health Reference Level (HRL) of 15 µg/L based on the RfD of 0.7 µg/kg/day and body weight and exposure information for pregnant women (USEPA, 2008a). Using the UCMR 1 occurrence data, the EPA estimated that less than 1% of drinking water systems (serving approximately 1 million people) had perchlorate levels above the HRL of 15 µg/L. Based on this information, the EPA found that perchlorate did not occur at a frequency and at levels of public health concern. The EPA also determined there was not a meaningful opportunity for a NPDWR for perchlorate to reduce health risks.

In August 2009, the EPA published a supplemental request for comment with new analysis that derived potential alternative Health Reference Levels (HRLs) for 14 life stages, including infants and children. The analysis used the RfD of 0.7 µg/kg/day and life stage-specific bodyweight and exposure information, resulting in comparable perchlorate concentrations in drinking water, based on life stage, of between 1 µg/l to 47 µg/l (74 FR 41883; USEPA, 2009a).

In February 11, 2011, the EPA published its determination to regulate perchlorate (76 FR 7762; USEPA, 2011) after careful consideration of public comments on the October 2008 and August 2009 notices. The EPA found at that time that perchlorate may have an adverse effect on the health of persons; that it is known to occur, or that there is a substantial likelihood that it will occur, in public drinking water systems with a frequency and at levels that present a public

health concern; and that regulation of perchlorate presented a meaningful opportunity for health risk reduction for persons served by public water systems. The EPA found that as many as 16 million people could potentially be exposed to perchlorate at levels of concern, up from 1 million people originally estimated in the 2008 notice.

As a result of the determination, and as required by SDWA 1412(b)(1)(E), the EPA initiated the process to develop a MCLG and a NPDWR for perchlorate.

In September 2012, the U.S. Chamber of Commerce (the Chamber) submitted to the EPA a Request for Correction under the Information Quality Act regarding the EPA's regulatory determination². In the request, the Chamber claimed that the UCMR 1 data used in the EPA's occurrence analysis did not comply with data quality guidelines and were not representative of current conditions. In response to this request, the EPA reassessed the data and removed certain source water samples that could be paired with appropriate follow-up samples located at the entry point to the distribution system. The EPA also updated the UCMR 1 data in the analysis for systems in California and Massachusetts, using state compliance data to reflect current occurrence conditions after state regulatory limits for perchlorate were implemented. For more

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² The U.S. Chamber of Commerce letter to the EPA and other corresponding records are available at https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration#12004.

information on the Chamber's request and the EPA's response, see the Perchlorate Occurrence and Monitoring Report (USEPA, 2019b).

As required by section 1412(d) of the SDWA, as part of the NPDWR development process, the EPA requested comments from the Science Advisory Board (SAB) in 2012, seeking guidance on how best to consider and interpret the life stage information, the epidemiologic and biomonitoring data since the NRC report, physiologically-based pharmacokinetic (PBPK) analyses, and the totality of perchlorate health information to derive an MCLG for perchlorate. In May 2013, the SAB recommended that the EPA:

- derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling based upon its mode of action, rather than the default MCLG approach using the RfD and specific chemical exposure parameters;
- expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;
- utilize a mode-of-action framework for developing the MCLG that links the steps in the
 proposed mechanism leading from perchlorate exposure through iodide uptake inhibition—to
 thyroid hormone changes—and finally to neurodevelopmental impacts; and
- "[e]xtend the [BBDR] model expeditiously to . . . provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide

deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages" (SAB for the U.S. EPA, 2013, p. 19).

To address the SAB recommendations, the EPA revised an existing PBPK/PD model that describes the dynamics of perchlorate, iodide, and thyroid hormones in a woman during the third trimester of pregnancy (Lumen, Mattie, & Fisher, 2013; USEPA, 2009b). The EPA also created its own Biologically Based Dose Response (BBDR) models that included the additional sensitive life stages identified by the SAB, *i.e.*, breast- and bottle-fed neonates and infants (SAB for the U.S. EPA, 2013, p. 19).

To determine whether the Agency had implemented the SAB recommendations for modeling thyroid hormone changes, the EPA convened an independent peer review panel to evaluate the BBDR models in January 2017 (External Peer Reviewers for USEPA, 2017). The EPA considered the recommendations from the 2017 peer review and made necessary model revisions to increase the scientific rigor of the model and the modeling results, including extending the BBDR model to the first trimester and incorporating the TSH feedback mechanism.

The EPA convened a second independent peer review panel in January 2018 to evaluate the revisions to the BBDR model, including the transition from the third to the first trimester as the life stage of interest. The EPA also presented several approaches to link the thyroid hormone changes in a pregnant mother predicted by the BBDR model to neurodevelopmental effects using evidence from the epidemiological literature (External Peer Review for U.S. EPA, 2018).

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In response to a lawsuit brought to enforce the deadlines in SDWA 1412(b)(1)(E) triggered by the 2011 regulatory determination for perchlorate, on October 18, 2016, the U.S. District Court for the Southern District of New York entered a consent decree, requiring the EPA to sign for publication a proposal for a MCLG and NPDWR for perchlorate in drinking water no later than October 31, 2018, and to sign for publication a final MCLG and NPDWR for perchlorate in drinking water no later than December 19, 2019. The deadline for the EPA to propose a MCLG and NPDWR for perchlorate in drinking water was later extended to May 28, 2019, and the date for signature of a final MCLG and NPDWR was extended to no later than June 19, 2020. The consent decree is available in the docket for this action.

In compliance with the deadline established in the consent decree, on May 23, 2019, the EPA Administrator signed a proposed rulemaking document seeking public comment on a range of options regarding the regulation of perchlorate in public drinking water systems. The proposed rulemaking document was published in the *Federal Register* on June 26, 2019. 84 FR 30524. The EPA proposed a NPDWR for perchlorate with an MCL and MCLG of 56 μg/L. The proposed MCLG of 56 μg/L was based on avoiding an estimated 2 point IQ decrement associated with exposure to perchlorate in drinking water during the most sensitive life stage (the fetus) within a specific segment of the population (iodine deficient pregnant women).

The EPA also requested comment on two alternative MCL/MCLG values of 18 µg/L and 90 µg/L. These alternatives were based upon avoiding an estimated 1 point and 3 point IQ decrement respectively, associated with perchlorate exposure. Additionally, the EPA requested

comment on whether the 2011 regulatory determination should be withdrawn, based on new information including updated occurrence data on perchlorate in drinking water and new analysis of the concentration of perchlorate in drinking water that represents a level of health concern.

III. Withdrawal of the 2011 Regulatory Determination and Final Determination Not to Regulate Perchlorate

In determining whether to regulate a particular contaminant, the EPA must follow the criteria mandated by the 1996 SDWA Amendments. Specifically, in order to issue a MCLG and NPDWR for perchlorate, the EPA must determine that perchlorate "may have an adverse effect on the health of persons," that perchlorate occurs at "a frequency and at levels of public health concern" in public water systems, and that regulation of perchlorate in drinking water systems "presents a meaningful opportunity for health risk reduction for persons served by public water systems." SDWA 1412(b)(1)(A). In preparing the 2019 proposal for perchlorate, the EPA updated and improved information on the levels of public health concern and the frequency and levels of perchlorate in public water systems. The following is the EPA's reassessment of the regulatory determination criteria applied to the best available health science and occurrence data for perchlorate.

A. May perchlorate have an adverse effect on the health of persons?

Yes, perchlorate may have adverse health effects above certain exposure levels.

The perchlorate anion is biologically significant specifically with respect to the functioning of the thyroid gland. Above certain exposure levels, perchlorate can interfere

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with the normal functioning of the thyroid gland by inhibiting the transport of iodide into the thyroid, resulting in a deficiency of iodide in the thyroid. Perchlorate inhibits (or blocks) iodide transport into the thyroid by chemically competing with iodide, which has a similar shape and electric charge. The transfer of iodide from the blood into the thyroid is an essential step in the synthesis of thyroid hormones. Thyroid hormones play an important role in the regulation of metabolic processes throughout the body and are also critical to developing fetuses and infants, especially for brain development. Because the developing fetus depends on an adequate supply of maternal thyroid hormones for its central nervous system development during the first and second trimester of pregnancy, iodide uptake inhibition from perchlorate exposure has been identified as a concern in connection with increasing risk of neurodevelopmental impairment in fetuses of pregnant women with low dietary iodine. Poor iodide uptake and subsequent impairment of the thyroid function in pregnant and lactating women have been linked to delayed development and decreased learning capability in their infants and children (NRC, 2005). There is scientific evidence to support that perchlorate can reduce iodide uptake and therefore alter the level of thyroid hormones. There is also scientific evidence that changes in thyroid hormone levels in a pregnant woman may be linked to changes in the neurodevelopment of her offspring. The existence of a quantifiable relationship between thyroid hormone changes and neurodevelopmental outcomes has strong support from the literature on the subject; however, not every study identifies an association between

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maternal thyroid hormone levels and the neurodevelopmental outcomes and the state of the science on this relationship is constantly evolving.

Therefore, the EPA continues to find that perchlorate may have an adverse effect on the health of persons above certain exposure levels based on its ability to interfere with thyroid hormone production.

B. Is perchlorate known to occur or is there a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern?

The EPA has determined that perchlorate does not occur with a frequency and at levels of public health concern in public water systems. The EPA has made this determination by comparing the best available data on the occurrence of perchlorate in public water systems with potential MCLGs for perchlorate.

In past regulatory determinations, the EPA has identified HRLs as benchmarks against which the EPA compares the concentration of a contaminant found in public water systems to determine whether it occurs at levels of public health concern. For the 2011 regulatory determination, the EPA identified potential alternative HRL values ranging from 1 to 47 µg/L for 14 different life stages. These HRLs were not final decisions about the level of perchlorate in drinking water that is without adverse effects. For the 2019 proposal, the EPA derived three potential MCLGs for perchlorate of 18, 56, and 90 µg/L for the most sensitive life stage using the best available peer reviewed science in accordance with the SDWA. After considering public comment, the EPA used these potential MCLGs as the levels of public health concern in assessing the frequency of occurrence of perchlorate in this regulatory determination. These

MCLGs were set at levels to avoid estimated IQ decrements of 1, 2, and 3 points respectively in the most sensitive life stage, the children of hypothyroxinemic women with low iodine intake. The EPA proposed an MCLG of 56 μ g/L and alternative MCLG values of 18 and 90 μ g/L.

The rationale used in deriving the numerical values is presented in greater detail in the EPA technical support document entitled "Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" (USEPA, 2019a).

The EPA compared these potential MCLG values with the updated perchlorate UCMR 1 occurrence data set. A comprehensive description of the perchlorate occurrence data is presented in Section VI of the 2019 proposal. It is also available in the "Perchlorate Occurrence and Monitoring Report" (USEPA, 2019a).

The occurrence data for perchlorate were collected from 3,865 PWSs between 2001 and 2005 under the UCMR 1. In the 2019 proposal, the EPA modified the UCMR 1 data set in response to concerns raised by stakeholders regarding the data quality and to represent current conditions in California and Massachusetts, which have enacted perchlorate regulations since the UCMR 1 data were collected. Massachusetts promulgated a drinking water standard for perchlorate of 2 µg/L in 2006 (MassDEP, 2006), and California promulgated a drinking water standard of 6 µg/L in 2007 (California Department of Public Health, 2007). Systems in these states are now required to keep perchlorate levels in drinking water below their state limits. As discussed below, the EPA finds that perchlorate levels in drinking water and sources of drinking water have decreased since the UCMR 1 data collection. The main factors contributing to the

decrease in perchlorate levels are the promulgation of drinking water regulations for perchlorate in California and Massachusetts and the ongoing remediation efforts in the state of Nevada to address perchlorate contamination in groundwater adjacent to the lower Colorado River upstream of Lake Mead.

To update the occurrence data for systems sampled during UCMR 1 from California and Massachusetts, the EPA identified all systems and corresponding entry points which had reported perchlorate detections in UCMR 1. Once the systems and entry points with detections were appropriately identified, the EPA then used publicly available California and Massachusetts monitoring data for perchlorate, to replace the original UCMR1 data with more recent data where available (Perchlorate Occurrence and Monitoring Report, USEPA, 2019b).

The EPA has determined that the UCMR 1 data with these updates are the best available data collected in accordance with accepted methods regarding the frequency and level of perchlorate nationally. The UCMR 1 data are from a census of the large water systems (serving more than 10,000 people) and a statistically representative sample of small water systems that provides the best available, national assessment of perchlorate occurrence in drinking water.

The EPA used entry point maximum measurements to estimate potential baseline occurrence and exposure at levels that exceed the potential MCLG thresholds. The maximum measurements indicate highest perchlorate levels reported in at least one quarterly sample from surface water systems and at least one semi-annual sample from ground water systems.

Table 1: Perchlorate Occurrence and Exposure (Updated UCMR 1 Data Set)

Threshold Concentration (µg/L)	Entry Points with Detections above Threshold	Water Systems with Detections above Threshold	Percent of U.S. Water Systems with Detections above Threshold	Population Served
18 μg/L	17	15	0.03 %	620,560
56 μg/L	2	2	0.004 %	32,432
90 μg/L	1	1	0.002 %	25,972

Table 1 presents the number and percentage of water systems that reported perchlorate at levels exceeding the three proposed MCLG threshold concentrations. In summary, the updated perchlorate occurrence information suggests that at an MCLG of 18 μg/L, there would be 15 systems (0.03% of all water systems in the U.S.) that would exceed the threshold, at an MCLG of 56 μg/L, two systems (0.004% of all water systems in the U.S.) would exceed the threshold, and finally one system would exceed the MCLG threshold of 90 μg/L. Based on the analysis of drinking water occurrence presented in the 2019 proposal and the data summarized in Table 1 and the range of potential MCLGs, the EPA concludes that perchlorate does not occur with a frequency and at levels of public health concern in public water systems.

The EPA notes that in 2008, the EPA stated in its preliminary regulatory determination that perchlorate did not occur with a frequency and at levels of public health concern in public water systems based upon the health effects and occurrence information available at that time, which indicated that 0.8% of public water system had perchlorate at levels exceeding the HRL of 15 mg/L. The EPA also stated that there was not a meaningful opportunity for a NPDWR to

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reduce health risks based upon the estimates at that time that 0.9 million people had perchlorate levels above the HRL. The EPA further notes that the Agency has previously determined CCL1 and CCL2 contaminants did not occur with frequency at levels of public health concern when the percentage of water systems exceeding the HRL were greater than the frequency of perchlorate occurrence level at the proposed MCL (0.004% of all water systems in the U.S.). For example, in 2003 the EPA determined that aldrin did not occur with a frequency and at levels of public health concern based upon data that showed 0.2% of water systems had aldrin at levels greater than the HRL. The EPA also concluded that there was not a meaningful opportunity for health risk reduction for persons served through a drinking water regulation based on this occurrence data and the estimate that these systems above the HRL served approximately 1 million people (USEPA, 2003). In 2008 the EPA determined that DCPA Mono- and Di-Acid degradates did not occur with a frequency and at levels of public health concern based on data that showed 0.03% of water systems exceeded the HRL. The EPA also concluded that there was not a meaningful opportunity for health risk reduction through a drinking water regulation based on this occurrence data and the estimate that these systems above the HRL served approximately 100,000 people (USEPA, 2008b).

While the EPA has made its conclusion that perchlorate does not occur at a frequency and at levels of public health concern in public water systems based on the updated UCMR 1 data in Table 1 above, the EPA also sought to find additional information about the perchlorate levels at the 15 water systems that had at least one reported result greater than $18 \mu g/L$ in the

updated UCMR 1 data. The EPA found that perchlorate levels have been reduced at many of these water systems. Although these water systems were not required to take actions to reduce perchlorate in drinking water, many had conducted additional monitoring for perchlorate and found decreased levels or had taken mitigation efforts to address perchlorate, confirming the EPA's conclusion described above. The status of each of these systems is described in Table 2 below and confirms the Agency's conclusion that is based upon the information in Table 1.

Table 2: Update on Systems with Perchlorate levels above 18 μg/L in the UCMR 1

State	System Name	Range of UCMR 1 Results (µg/L)**	Update on Mitigation and Levels of Perchlorate ⁺⁺	
Florida	Sebring Water	ND-70	The EPA contacted the Sebring system in January 2020. Operations personnel indicated that no follow-up/updated monitoring data for perchlorate are available.	
Florida	Manatee County Utilities Dept	ND-30	Researchers contacted the system to identify the source of perchlorate. System personnel attributed the sole perchlorate detection under UCMR 1 to analytical error. System personnel indicated that three other quarterly samples collected under UCMR 1 as well as other subsequent perchlorate sampling efforts were non-detect. Source: AWWA (2008)	
Georgia	Oconee Co Watkinsville	38 (single sample)	Researchers contacted the system and found that a perchlorate contaminated well was removed from service in 2003. The system indicates that perchlorate is no longer detected. Source: Luis et al. (2019)	
Louisiana	St. Charles Water District 1 East Bank	ND-24	The EPA was not able to identify updated data on perchlorate levels for this system.	

State	System Name	Range of UCMR 1 Results (µg/L)**	Update on Mitigation and Levels of Perchlorate ⁺⁺
Maryland	City of Aberdeen	ND-19	The system's 2018 Consumer Confidence Report (CCR) indicates that perchlorate was not detected. According to the Maryland Department of Environment, perchlorate was not detected in this system in 2019. In addition, researchers contacted the system and found that there has been no detection of perchlorate since treatment was installed in 2009. Source: Luis et al. (2019)
Maryland	Chapel Hill - Aberdeen Proving Grounds	ND-20	The EPA contacted the Chapel Hill System in January 2020. Water system personnel indicate that the Chapel Hill WTP was taken off-line and was replaced with a new treatment plant and five new production wells. The new treatment plant started operations on January 27, 2020. System personnel also indicate that monitoring was conducted in November 2019 and perchlorate was not detected in either the source well water or the finished water. In addition, according to the Maryland Department of Environment, perchlorate was not detected in this system in 2019.
Mississippi	Hilldale Water District	ND-20	The EPA contacted the Hilldale System in January 2020. Water system personnel indicated that no follow-up/updated monitoring data for perchlorate are available.
New Mexico	Deming Municipal Water System	15-20	Data from the EPA's SDWIS/FED database indicates that the entry point that reported detections in UCMR 1 (Well #3) is now inactive (i.e., the contaminated source is no longer in use).
Nevada	City of Henderson	6-23	Researchers report that the perchlorate levels described in the system's CCR ranged from non-detect to 9.7 µg/L. Source AWWA (2008).

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State	System Name	Range of UCMR 1 Results (µg/L)**	Update on Mitigation and Levels of Perchlorate ⁺⁺
Ohio	Fairfield City PWS	6-27	The EPA contacted the Fairfield City System in January 2020. Water system personnel indicated that follow-up monitoring was conducted after UCMR 1, between 2002 and 2004. The Ohio EPA provided copies of the follow-up monitoring results which indicate that results at the entry point ranged from non-detect to 13 μ g/L.
Ohio	Hecla Water Association-Plant PWS	ND-32	The EPA contacted the Hecla Water Association System in January 2020. Water system personnel indicated that that no follow-up/updated monitoring data for perchlorate are available.
Oklahoma	Enid	ND-30	The EPA reviewed Oklahoma's monitoring data and did not find any monitoring results reported for perchlorate.
Pennsylvania	Meadville Area Water Authority	ND-33	The EPA contacted the Meadville System in January 2020. Water system personnel indicated that no follow-up/updated monitoring data for perchlorate are available.
Puerto Rico	Utuado Urbano	ND-420	The EPA contacted the Puerto Rico Aqueduct and Sewer Authority (PRASA) in January 2019. PRASA personnel indicated that no updated monitoring data for perchlorate are available. NOTE: The PRASA personnel stated that the Utuado water system was significantly impacted by Hurricane Maria and that monitoring records from years prior to 2017 were lost.
Texas	City of Levelland	ND-32	Researchers found that a water storage tank was the source of perchlorate contamination The wells feeding the tank were tested by the state and perchlorate was not detected. The water tank was shut off from service. Source: Luis et al. (2019).

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- ** Values have been rounded. ND describes a sampling event where perchlorate was not detected at or above the UCMR 1 minimum reporting level of 4 μ g/L. UCMR 1 results collected between 2001 and 2005.
- ++ To obtain updated data and/or information regarding perchlorate levels, the EPA reviewed Consumer Confidence Reports and other publicly available data, as well as published studies. In addition, the EPA contacted some water systems for information about current perchlorate levels. (USEPA, 2020a)
- C. Is there a meaningful opportunity for the reduction of health risks from perchlorate for persons served by public water systems?

The EPA's analysis presented in the 2019 proposal demonstrates that a NPDWR for perchlorate does not present a meaningful opportunity for health risk reduction for persons served by public water systems. As discussed above, the EPA found that perchlorate occurs with very low frequency at levels of public health concern. Based on updated UCMR 1 occurrence information, there were 15 water systems (0.03% of all water systems in the U.S.) that detected perchlorate in drinking water above the lowest proposed alternative MCLG of 18 µg/L, and only 1 system had a detection above the proposed alternative MCLG of 90 µg/L. Specifically, Table 1 presents the population served by PWSs that were monitored under UCMR 1 for which the highest reported perchlorate concentration was greater than the identified thresholds. The EPA estimates³ that the number of people who may be potentially consuming water containing perchlorate at levels that could exceed the levels of concern for perchlorate could range between 26,000 and 620,000.

 $^{^3}$ The values shown in Table 1 are based on the revised UCMR 1 data. The EPA also applied statistical sampling weights to the small systems results to extrapolate to national results. There was one small system included in the statistical sample stratum which had a perchlorate measurement exceeding 18 $\mu g/L$. Accordingly, the EPA estimates that approximately 41,000 small system customers may be exposed to perchlorate greater than 18 $\mu g/L$. Page 28 of 50

The small number of water systems with perchlorate levels greater than identified thresholds, and the correspondingly small population served, provides ample support for the EPA's conclusion that the regulation of perchlorate does not present a "meaningful opportunity for health risk reduction for persons served by public water systems," within the meaning of SDWA 1412(b)(1)(A)(iii).

While the EPA does not believe that a national primary drinking water regulation presents a meaningful opportunity for health risk reduction, the Agency remains committed to working with States and communities in addressing perchlorate contamination of drinking water. For example, the EPA has issued a document entitled "Perchlorate Recommendations for Public Water Systems" which provides recommendations for actions that systems may take if there are concerns about perchlorate (USEPA, 2020b). The document outlines steps public systems can take to address perchlorate in drinking water, including testing, installing treatment equipment, and communication with customers.

Although a cost benefit analysis is not one of the three SDWA criteria for making a regulatory determination, the EPA also considered the findings of the Health Risk Reduction and Cost Analysis (HRRCA, USEPA 2019c) as additional information confirming the appropriateness of the withdrawal of the regulatory determination. The HRRCA for perchlorate (which was presented in the 2019 proposal) provides a unique set of economic data indicators that are not available for regulatory determinations because the HRRCA is required for a proposed NPDWR under SDWA 1412(b)(3)(C), but is not required to support a regulatory

determination. Accordingly, because the EPA initially determined that perchlorate met the criteria for regulation and began the regulatory analysis process, the HRRCA was available with respect to perchlorate at this stage in the SDWA process, and the Agency considered this comprehensive economic analysis in informing its decision to withdraw the regulatory determination.

Specifically, the HRRCA provides a description of the potential benefits and costs of a drinking water regulation for perchlorate. For all potential regulatory levels considered for perchlorate (18, 56, and 90 µg/L), the total costs associated with establishing a regulation (ranging from \$9.5 to \$18.0 million across discount rates and levels) were substantially higher than the potential range of benefits (ranging from \$0.3 to \$3.7 million) (USEPA, 2019c). The infrequent occurrence of perchlorate at levels of health concern imposes high monitoring and administrative cost burdens on public water systems and the states, while having little impact on health risk reductions and the associated low estimates of benefits. The EPA is not finalizing the HRRCA for this final action nor is the EPA conducting an analysis in accordance with the Regulatory Flexibility Act because the Agency is not promulgating a final regulation.

Based on a comparison of costs and benefits estimated at the three potential regulatory levels, the EPA determined in the 2019 proposal that the benefits of establishing a drinking water regulation for perchlorate do not justify the potential costs.

A drinking water regulation for perchlorate would impose significant burdens on states and water systems, mainly associated with requirements for monitoring, including initial

monitoring and long-term monitoring for over 60,000 systems (see Section VIII of the 2019 proposal for more information), but would result in very few systems having to take action to reduce perchlorate levels. It is of paramount importance that water systems (particularly medium, small, and economically distressed systems) focus their limited resources on actions that ensure compliance with existing NPDWRs and maintain their technical, managerial, and financial capacity to improve system operations and the quality of water being provided to their customers, rather than spending resources monitoring for contaminants that are unlikely to occur.

D. What is the EPA's final regulatory determination on perchlorate?

Based on the EPA's analysis of the best available public health information, and after careful review and consideration of public comments on the June 2019 proposal, the Agency is withdrawing its 2011 determination and is making a final determination not to regulate perchlorate. Accordingly, the EPA will not issue a NPDWR for perchlorate at this time. While the EPA has found that perchlorate may have an adverse effect on human health above certain exposure levels, based on the analysis presented in this document and supporting record, the EPA has determined that perchlorate does not occur in public water systems with a frequency and at levels of public health concern and that regulation of perchlorate does not present a meaningful opportunity to reduce health risks for persons served by public water systems. This conclusion is based on the best available peer reviewed science and data collected in accordance with accepted methods on perchlorate health effects and occurrence.

IV. Summary of Key Public Comments on Perchlorate

The EPA received approximately 1,500 comments from individuals or organizations on the June 2019 proposal. This section briefly discusses the key technical issues raised by commenters and the EPA's response. Comments are also addressed in the "Comment Response Document for the Final Regulatory Action for Perchlorate" (USEPA, 2020c) available at http://www.regulations.gov (Docket ID No. EPA–HQ–OW–2018–0780).

A. SDWA Statutory Requirements and the EPA's Authority

The EPA received comments stating that the Agency should promulgate an MCLG and MCL for perchlorate and comments stating that the Agency should not promulgate a regulation. After considering these comments, the EPA has re-evaluated perchlorate in accordance with SDWA 1412(b)(1)(A), which requires that the Agency promulgate a NPDWR if (i) the contaminant may have an adverse effect on the health of persons; (ii) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and (iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

The EPA has determined, based upon the best available peer reviewed science and data collected in accordance with accepted methods, that perchlorate does not occur at a frequency and at levels of public health concern, and that regulation of perchlorate does not present a meaningful opportunity for health risk reduction. Because perchlorate does not meet the statutory

criteria for regulation, the EPA lacks the authority to issue a MCLG or NPDWR for perchlorate, and, is therefore withdrawing its 2011 regulatory determination and issuing this final determination not to regulate perchlorate. For more information regarding the EPA's statutory authority to withdraw its regulatory determination, see Section II.C above.

B. Health Effects Assessment

Health Effects/MCLG Derivation

The EPA received comments indicating that the Agency should utilize different approaches to derive the MCLG for perchlorate including approaches that some states used to develop their perchlorate advisory levels or drinking water standards. The EPA considered a number of alternative approaches to develop the MCLG for perchlorate and in accordance with SDWA 1412(e), the Agency sought recommendations from the Science Advisory Board. The EPA derived the proposed MCLG for perchlorate based on the approach recommended by the Science Advisory Board (SAB) (SAB for the U.S. EPA, 2013). The SAB recommended that "the EPA derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling based upon its mode of action rather than the default MCLG approach using the RfD and specific chemical exposure parameters." The EPA has implemented these recommendations and has obtained two independent peer reviews of the analysis. These peer reviewers stated that: "[o]verall, the panel agreed that the EPA and its collaborators have prepared a highly innovative state-of-the-science set of quantitative tools to evaluate neurodevelopmental effects that could arise from drinking water exposure to

perchlorate. While there is always room for improvement of the models, with limited additional work to address the committee's comments below, the current models are fit-for-purpose to determine an MCLG' (External Peer Reviewers for USEPA, 2018, p. 2).

The EPA received comments indicating that the most sensitive life stages were not selected and/or considered in the Agency's approach. The EPA disagrees. Gestational exposure to perchlorate during neurodevelopment is the most sensitive time period. The NRC concluded that the population most sensitive to perchlorate exposure are "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" (p. 178, NRC 2005). In addition, there is clear evidence that disrupted maternal thyroid hormone levels during gestation can impact neurodevelopment later in life (Alexander et al., 2017; Costeira et al., 2011; Endendijk et al., 2017; Ghassabian, Bongers-Schokking, Henrichs, Jaddoe, & Visser, 2011; Glinoer & Delange, 2000; Glinoer & Rovet, 2009; Gyllenberg et al., 2016; Henrichs et al., 2010; Korevaar et al., 2016; Morreale de Escobar, Obregón, & Escobar del Rey, 2004; Noten et al., 2015; Pop et al., 2003, 1999; SAB for the U.S. EPA, 2013; Thompson et al., 2018; van Mil et al., 2012; Wang et al., 2016; Zoeller & Rovet, 2004; Zoeller et al., 2007). The available data demonstrate that the fetus of the first trimester pregnant mother, when compared to other life-stages, experiences the greatest impact from the same dose of perchlorate, which is described in detail in Section 6 of the document "Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" (USEPA, 2019a). Some commenters suggested that the bottle-fed infant is a more sensitive lifestage. The EPA disagrees. As described in the January 2017 Peer Review Report on the original

Biologically Based Dose Response (BBDR) model, the bottle-fed infant's thyroid hormone levels were not impacted by doses of perchlorate up to $20 \mu g/day$ (External Peer Reviewers for USEPA, 2017). This lack of any impact is due primarily to the iodine in the formula, which offsets the impact of perchlorate on the thyroid.

The EPA received comments advocating for the use of the population-based approach evaluating the shift in the proportion of a population that would fall below a hypothyroxinemic cut point under a perchlorate exposure scenario. The EPA chose to develop the MCLG using dose-response functions from the epidemiological literature to estimate neurodevelopmental impacts in the offspring of pregnant women exposed to perchlorate. The EPA selected this proposed approach because it is consistent with the SDWA's definition of a MCLG to avoid adverse health effects and because it is most consistent with the SAB recommendations. In addition, given that thyroid hormone levels vary by reference population and that there is not a defined threshold for the concentration of fT4 representing hypothyroxinemia makes the population-based approach less desirable than the approach selected (USEPA, 2018).

End Point Selection/Basis

The EPA received comments regarding the magnitude of an IQ change which should be used in deriving the MCLG. The EPA's proposed MCLG was based upon avoiding a 2% change in IQ in the most sensitive life stage, and the EPA also requested comment on alternative options for the MCLG that would respectively avoid 1% or 3% change in IQ in the most sensitive life stage. Many comments stated that the EPA should at most consider a 1% IQ change. However,

several commenters stated that a 3% change is too small to have a meaningful impact and suggested that the EPA consider a higher IQ percent change.

The EPA uses a variety of science policy approaches to select points of departure for developing regulatory values. For instance, in noncancer risk assessment, the EPA often uses a percentage change in value. When assessing toxicological data, a 10 % extra risk (for discrete data), or a 1 standard deviation (i.e., 15 IQ points) change from the mean (for continuous data) is often used (USEPA, 2012). A smaller response to inform a POD has been applied when using epidemiological literature, because there is an inherently more direct relationship between the study results and the exposure context and health endpoint.

Given the difficulty in identifying a response below which no adverse impact occurs when considering a continuous outcome in the human population, the EPA looked to its Benchmark Dose Guidance (2012) for insight regarding a starting point. Specifically, "[a] BMR of 1% has typically been used for quantal human data from epidemiology studies" (p. 21, USEPA, 2012). For the specific context of setting an MCLG for perchlorate, the EPA evaluated the level of perchlorate in water associated with a 1% decrease, a 2% decrease, and a 3 percent decrease in the mean population IQ (i.e., 1, 2 and 3 IQ points).

In evaluating the frequency and level of occurrence of perchlorate in drinking water, the EPA has found that perchlorate does not occur with frequency even at the lowest alternative MCLG of 18 μ g/L, which is based upon avoiding a 1% change in IQ in the most sensitive life stage.

The EPA received comments that the proposed MCLG did not incorporate an adequate margin of safety to comply with the SDWA. The EPA disagrees that it failed to use an adequate margin of safety. The EPA's assessment focused upon the most sensitive subset of the population, specifically offspring whose mothers had low (75 µg/day) iodine intake and were hypothyroxinemic (fT4 in the lowest 10th percentile of the population). In addition, to account for uncertainties and to ensure that the most sensitive subset of the population is protected with an adequate margin of safety, a 3-fold uncertainty factor was applied to the proposed MCLG calculation (USEPA, 2019a). More discussion on the uncertainty factor is presented below, in the section entitled "Consideration of Uncertainties."

The EPA received some comments stating that the selection of the study for informing the relationship between maternal hormone levels (fT4) and IQ was inadequately described. Other comments supported the EPA's study selection. The EPA concludes that selection of the Korevaar et al. (2016) study is appropriate because that study provides the most robust data available with a clear measure of neurodevelopment that can be expressed as a function of changing maternal fT4 exposure, which is necessary to the development of the model.

BBDR and PBPK Models

The EPA received comments indicating that the BBDR model was not transparent, scientifically valid, or based on robust data. The EPA disagrees. The model represents the best available peer reviewed science and uses the best available data to inform a MCLG for perchlorate. The EPA disagrees with the suggestion that there is a significant lack of

transparency with respect to the assumptions related to the BBDR model. Appendix A of the EPA's Proposed MCLG Approaches report outlines the justification for all assumptions used in the development of the BBDR model (USEPA, 2019a). The EPA also disagrees with the assertion that the BBDR model is far too uncertain to be relied upon as the basis for the derivation of the RfD. The EPA has used the best available science to calibrate the pharmacokinetic aspects of the BBDR model. The development of the BBDR model was in response to SAB recommendations, and a model was deemed to be a more refined approach to estimating a dose-response relationship between perchlorate exposure and maternal fT4 than anything that was available in the current scientific literature. The EPA disputes the claim that the BBDR model is not scientifically valid, as the Agency conducted a peer review of the approach proposed and the reviewers concluded that the approach was "fit for purpose" to inform a MCLG for perchlorate (External Peer Reviewers for U.S. EPA, 2018, p. 2).

Consideration of Uncertainties

The EPA received comments on the Agency's use of Uncertainty factors (UFs); with most commenters suggesting that the EPA should consider a higher UF for inter-individual variability. The EPA thoroughly considered the application of UFs when deriving the RfDs and followed guidance presented in "A review of the reference dose and reference concentration processes" (USEPA, 2002). The EPA concluded that the UFs are adequately justified, and subsequently no changes have been made. Justification for each of the UFs can be found in Section 11 of the Agency's MCLG Derivation report (USEPA, 2019a).

The EPA selected a UF of 3 for inter-individual variability, because the Agency specifically modeled groups within the population that are identified as likely to be at greater risk of the adverse effects from perchlorate in drinking water (i.e., the fetus of the iodide deficient pregnant mother). The EPA selected model parameters to account for the most sensitive individuals in that group (i.e., muted TSH feedback, low fT4 values, low-iodine intake). As discussed in the MCLG Derivation report, the EPA has attempted to select the most appropriate inputs to protect the most sensitive population with an adequate margin of safety (USEPA, 2019a). The EPA has determined that the selection of a UF of 3 for inter-individual variability is justified. As described in the MCLG Derivation report, because the output from the BBDR model is specific to the sensitive population, the EPA concluded that the UF of 3 is appropriate. In regard to variation in sensitivity among the members of the human population (i.e., interindividual variability), section 4.4.5.3 of the EPA guidance "A review of the reference dose and reference concentration process" (USEPA, 2002) document states, "In general, the Technical Panel reaffirms the importance of this UF, recommending that reduction of the intraspecies UF from a default of 10 be considered only if data are sufficiently representative of the exposure/dose-response data for the most susceptible subpopulation(s). Similar to the interspecies UF, the intraspecies UF can be considered to consist of both a toxicokinetic and toxicodynamic portion (i.e. 10\^0.5 each)" (USEPA, 2002). Given that the BBDR model significantly accounts for differences within the human population, the full UF of 10 is not warranted.

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One commenter suggested using a UF greater than 1 to account for the extrapolation of the lowest-observed adverse effect level (LOAEL) to the no-observed-adverse-effect-level (NOAEL). LOAELs and NOAELs were not identified or used by the EPA in its assessment because the Agency employed a sophisticated BBDR modeling approach, which was coupled with extrapolation to changes in IQ using linear regression, to determine a POD that would not be expected to represent an adverse effect. Therefore, a UF of 1 is appropriate. Other commenters suggested incorporating UFs for database deficiencies. Based on the findings of the NRC report, the EPA has previously concluded that this UF was not needed for deficiencies in the perchlorate database (NRC, 2005; USEPA, 2005a). The EPA determined that a UF of 1 to account for database deficiencies is still appropriate, given that the comprehensiveness of the perchlorate database has only increased since 2005.

Health Advisory

Several commenters suggest that the EPA should withdraw the 2011 determination to regulate perchlorate and instead issue an updated health advisory for perchlorate. The EPA issued an interim health advisory level for perchlorate in 2008. Health advisories provide information on contaminants that can cause human health effects and are known or anticipated to occur in drinking water. The EPA's health advisories are non-enforceable and non-regulatory and provide technical information to state agencies on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination. State and local public health officials

have the discretion to use the perchlorate health advisory as they deem necessary. The EPA will consider updating the 2008 perchlorate health advisory in the future.

C. Occurrence Analysis

The EPA received comments suggesting that the revised UCMR 1 data did not provide an adequate estimate of the perchlorate occurrence in drinking water systems. Some commenters indicated that the age of the collected data rendered the occurrence analysis obsolete and overestimated, because it no longer captures current lower contamination conditions that have been achieved due to mitigation measures taken in the Colorado River Basin. Other commenters criticized the EPA for replacing UCMR 1 data for systems located in the States of California and Massachusetts with more recent state compliance data for perchlorate.

The EPA recognizes that changes in perchlorate levels (increasing or decreasing) may have occurred in water systems since the UCMR 1 samples were collected between 2001 to 2005. The EPA updated the UCMR 1 data set to improve its accuracy in representing the current conditions for states that have enacted perchlorate regulations since the UCMR 1 monitoring was conducted. As outlined in the June 26, 2019 proposal, the EPA updated occurrence data for California and Massachusetts with current compliance data as reported by the states. Systems from these two states that were sampled during the UCMR 1 and that had reported perchlorate detections were updated with more recently measured values taken from current compliance monitoring data from Consumer Confidence Reports and state-level perchlorate compliance monitoring data to match corresponding water systems and entry points.

The EPA has determined that the updated UCMR 1 data are the best available data collected in accordance with accepted methods on the frequency and level of perchlorate occurrence in drinking water on a national scale.

V. Conclusion

With this withdrawal of the 2011 perchlorate regulatory determination and final determination not to regulate perchlorate, the EPA announces that there will be no NPDWR for perchlorate at this time. The EPA could consider re-listing perchlorate on the CCL and could proceed to regulation in the future if the occurrence or health risk information changes. As with other unregulated contaminants, the EPA will consider addressing limited instances of elevated levels of perchlorate by working with the affected system and state, as appropriate.

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List of Subjects

40 CFR Part 141

Environmental protection, Administrative practice and procedure, Chemicals, Indians-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

Environmental protection, Administrative practice and procedure, Chemicals, Indians-lands, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Andrew Wheeler,

Administrator.





TECHNICAL FACT SHEET - PERCHLORATE

At a Glance

- Both naturally occurring and manmade anion.
- Contamination has been found at sites involved in the manufacture, maintenance, use and disposal of ammunition and rocket fuel.
- Highly soluble in water; migrates quickly from soil to groundwater.
- Primary pathways for human exposure include ingestion of contaminated food and drinking water.
- Affects thyroid gland by interfering with iodide uptake.
- EPA issued Interim Drinking Water Health Advisory.
- Various states have screening values or cleanup goals for perchlorate in drinking water or groundwater.
- Various detection methods available
- Common treatment technologies include ion exchange, bioremediation and membrane technologies.

Introduction

This fact sheet, developed by the U.S. Environmental Protection Agency (EPA) Federal Facilities Restoration and Reuse Office (FFRRO), provides a summary of the contaminant perchlorate, including physical and chemical properties; environmental and health impacts; existing federal and state guidelines; detection and treatment methods; and additional sources of information. This fact sheet provides basic information on perchlorate to site managers and other field personnel who are addressing perchlorate contamination at cleanup sites or in drinking water supplies.

What is perchlorate?

- Perchlorate is a naturally occurring and man-made anion that consists of one chlorine atom bonded to four oxygen atoms (ClO₄-). Manufactured forms of perchlorate include perchloric acid and salts such as ammonium perchlorate, sodium perchlorate and potassium perchlorate (EPA FFRRO 2005; ITRC 2005).
- Perchlorate is commonly used in solid rocket propellants, munitions, fireworks, airbag initiators for vehicles, matches and signal flares (EPA FFRRO 2005; ITRC 2005). It is also used in some electroplating operations (ATSDR 2008; ITRC 2005).
- Of the domestically produced perchlorate, 90 percent is manufactured for use in the defense and aerospace industries, primarily in the form of ammonium perchlorate (GAO 2005; ITRC 2005).
- Perchlorate may occur naturally, particularly in arid regions such as the southwestern United States (Rao and others 2007).
- Perchlorate is found as a natural impurity in nitrate salts from Chile, which are imported and used to produce nitrate fertilizers, explosives and other products (EPA FFRRO 2005; ITRC 2005).

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Exhibit 1: Physical and Chemical Properties of Perchlorate Compounds (ATSDR 2008; EPA FFRRO 2005; ITRC 2005; NIOSH 2014)

Property	Ammonium Perchlorate	Sodium Perchlorate	Potassium Perchlorate	Perchloric Acid
Chemical Abstracts Service (CAS) numbers	7790-98-9	7601-89-0	7778-74-7	7601-90-3
Physical description (physical state at room temperature)	White orthorhombic crystal	White orthorhombic deliquescent crystal	Colorless orthorhombic crystal or white crystalline powder	Colorless, oily liquid
Molecular weight (g/mol)	117.49	122.44	138.55	100.47
Water solubility (g/L at 25°C)	200	2,100	15	Miscible in cold water
Melting / Boiling point* (°C)	Melting point: 130	Melting point: 471 to 482	Melting point: 400 to 525	Melting point: -112 Boiling point: 19
Vapor pressure at 25°C (mm Hg)	Very low	Very low	Very low	N/A
Specific gravity (g/cm³)	1.95	2	2.52	1.77
Octanol-water partition coefficient (log K _{ow})	-5.84	-7.18	-7.18	-4.63

^{*}Different melting point temperatures are identified in literature.

Abbreviations: g/mol – grams per mole; g/L – grams per liter; °C – degrees Celsius; mm Hg – millimeters of mercury; g/cm³ – grams per cubic centimeter.

Existence of perchlorate in the environment

- Perchlorate is highly soluble in water, and relatively stable and mobile in surface and subsurface aqueous systems. As a result, perchlorate plumes in groundwater can be extensive (ITRC 2005). For example, the perchlorate plume at a former safety flare manufacturing site (the Olin Flare Facility) in Morgan Hill, California, extends 10 miles (Cal/EPA 2016b).
- Because of their low vapor pressure, perchlorate compounds and the perchlorate anion do not volatilize from water or soil surfaces to air (ATSDR 2008; ITRC 2005).
- Perchlorate released directly to the atmosphere is expected to readily settle through wet or dry deposition (ATSDR 2008).
- High concentrations of perchlorate have been detected at current and Formerly Used Defense Sites historically involved in the manufacture, testing and disposal of ammunition and rocket fuel or at industrial sites where perchlorate is manufactured or used as a reagent during operations (ATSDR 2008; ITRC 2005).
- Types of military and defense-related facilities with known releases include missile ranges and missile

- and rocket manufacturing facilities. However, since site-specific documentation may not be available and based on historical uncertainties, it is generally difficult to identify specific military sites with known perchlorate releases (ITRC 2005).
- From 1997 to 2009, the Department of Defense reported perchlorate detections at 284 (almost 70 percent) of its installations sampled (GAO 2010).
- In addition, the past disposal of munitions in either burial pits or by open burning and open detonation may have resulted in releases to the environment. The amount of perchlorate released can vary depending on the length of time the disposal area was used and the types of munitions disposed of in the area (ITRC 2005).
- Nitrate is commonly found as a co-contaminant in water with perchlorate because ammonium nitrate is a main component in rocket fuel and explosives (DoD ESTCP 2013).
- Studies have shown perchlorate accumulates in some food crop leaves, tobacco plants and in broad-leaf plants (ATSDR 2008).
- Surveys conducted by the U.S. Food and Drug Administration have detected perchlorate in food crops and milk (Murray and others 2008).

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- As of October 2009, perchlorate had been detected at varying levels in drinking water, groundwater, surface water, soil or sediment at private and federal facilities in 45 states, three U.S. territories and Washington D.C. The maximum concentrations reported in any media
- ranged from less than 4 parts per billion (ppb) to 2.6 million ppb (GAO 2010).
- EPA reported perchlorate detections at 40 hazardous waste sites on the EPA National Priorities List as of June 2010 (GAO 2010).

What are the routes of exposure and the potential health effects of perchlorate?

- Primary pathways for human exposure to perchlorate are ingestion of contaminated food and drinking water (ATSDR 2008; EPA FFRRO 2005).
- After perchlorate is ingested, it quickly passes through the stomach and intestines and enters the bloodstream (ATSDR 2008).
- The thyroid gland is the primary target of perchlorate toxicity in humans. Thyroid hormones play an important role in regulating metabolism and are critical for normal growth and development in fetuses, infants and young children. Perchlorate can interfere with iodide uptake into the thyroid gland at high enough exposures, disrupting the functions of the thyroid and potentially leading to a reduction in the production of thyroid hormones (ATSDR 2008; Cal/EPA 2015; National Research Council 2005).
- Potassium perchlorate was historically used to treat hyperthyroidism because of its ability to inhibit thyroid iodide uptake (ATSDR 2008; National Research Council 2005).
- Studies conducted on rodents showed that perchlorate concentrations below that required to alter thyroid hormone equilibrium are unlikely to cause thyroid cancer in human beings (ATSDR 2008; EPA IRIS 2005).
- Short-term exposure to high doses of ammonium, sodium or potassium perchlorate may cause eye, skin and respiratory tract irritation, coughing, nausea, vomiting and diarrhea. Perchloric acid is corrosive to the eyes, skin and respiratory tract, and short-term exposure to high doses may cause sore throat, coughing, labored breathing, deep burns, loss of vision, abdominal pain, vomiting or diarrhea (NIOSH 2014).

Are there any federal and state guidelines and health standards for perchlorate?

- EPA assigned perchlorate a chronic oral reference dose (RfD) of 0.0007 milligrams per kilogram per day (mg/kg/day). The RfD is an estimate of a daily exposure level that is likely to be without noncancer health effects over a lifetime (EPA IRIS 2005).
- The Agency for Toxic Substances and Disease Registry (ATSDR) has established a minimal risk level (MRL) of 0.0007 mg/kg/day for chronicduration oral exposure (365 days or more) to perchlorate. An MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health effects over a specified duration of exposure (ATSDR 2008, 2016).
- In 2011, EPA determined that perchlorate meets the Safe Drinking Water Act criteria for regulation as a contaminant. EPA then worked with the FDA to develop a dose-response model to analyze the effects of perchlorate on thyroid hormone production. In 2017, EPA completed a peer review to evaluate EPA's draft dose-response model. A future peer review will evaluate EPA's draft approach for deriving a Maximum Contaminant

- Level Goal (MCLG) for perchlorate in drinking water (EPA 2017a).
- In 2008, EPA established an Interim Drinking Water Health Advisory of 15 micrograms per liter (μg/L) for perchlorate. Exposure to this level for more than 30 days, but less than a year, is not expected to cause any adverse non-cancer effects. Health Advisories serve as informal guidance to assist managers of water systems; they are not legally enforceable standards (EPA 2008, 2012).
- EPA has calculated a tapwater screening level of 14 μg/L for perchlorate and perchlorate salts (EPA 2017b).
- EPA's Office of Land and Emergency Management recommends a preliminary remedial goal (PRG) of 15 μg/L at Superfund sites where there is an actual or potential drinking water exposure pathway, and where no applicable or relevant and appropriate requirements exist under federal or state laws (EPA 2009).
- California (6 μg/L) and Massachusetts (2 μg/L) have established enforceable standards for

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- perchlorate in drinking water (Cal/EPA 2016c; Massachusetts DEP 2016).
- Various states have adopted screening values or cleanup goals for perchlorate in drinking water or groundwater, ranging from 0.8 to 71 μg/L:

State	Guideline (ug/L)	Source
Alabama	24.5	ADEM 2008
California	1 (public health	Cal/EPA
	goal)	2016a
Colorado	4.9	CDPHE 2016
Florida	4	FDEP 2005
Illinois	4.9	IL EPA 2016
Indiana	15	IDEM 2016
Kansas	11 (residential) 71 (non-residential)	KDHE 2015
Maine	0.8	MDEP 2016
Maryland	2.6	MDE 2008
Nebraska	6.4	NDEQ 2012
Nevada	18	NDEP 2015
New Mexico	25.6	NMED 2012
Pennsylvania	15	PADEP 2011

State	Guideline (µg/L)	\$10,00000
Texas	17	TCEQ 2016
Utah	14	UDEQ 2012
Vermont	2 (interim preventive action level); 4 (interim enforcement standard)	VTDEC 2015
Virginia	15	VDEQ 2014
West Virginia	11	WVDEP 2014
Wyoming	23.3	WDEQ 2016

- EPA has calculated soil screening levels of 55 milligrams per kilogram (mg/kg) for residential areas and 820 mg/kg for industrial areas for perchlorate and perchlorate salts (ammonium, potassium, sodium and lithium) (EPA 2016b).
- Various states have adopted screening values or cleanup goals for perchlorate in soil, ranging from 0.1 to 150 mg/kg for residential areas, and from 5 to 2,000 mg/kg for industrial areas.

What detection and site characterization methods are available for perchlorate?

- Drinking water, groundwater and surface water:
 - EPA Method 314.0 Ion Chromatography (EPA 2016a)
 - EPA Method 314.1 Rev 1.0 Inline Column Concentration/Matrix Elimination Ion Chromatography with Suppressed Conductivity Detection (EPA 2016a)
 - EPA Method 314.2 Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection (EPA 2016a)
 - EPA Method 331.0 Rev. 1.0 Liquid Chromatography/Electrospray Ionization/Mass Spectrometry (EPA 2016a)
- Drinking water: EPA Method 332.0 Ion Chromatography with Suppressed Conductivity and Electrospray Ionization Mass Spectrometry (EPA 2016a)

- Surface water, groundwater, wastewater, salt water and soil: EPA SW-846 Method 6850 - High Performance Liquid Chromatography/Electrospray Ionization/Mass Spectrometry (EPA 2016c)
- Surface water, groundwater, salt water and soil: EPA SW-846 Method 6860 - Ion Chromatography/ Electrospray Ionization/Mass Spectrometry (EPA 2016c)
- The presence of high amounts of other anions, such as chloride, sulfate or carbonate, may interfere with the analysis of perchlorate (EPA 1999).
- Researchers have developed methods to distinguish man-made and natural sources of perchlorate in water samples using chlorine and oxygen stable isotope ratio analysis (Bŏhlke and others 2005; ITRC 2005; Sturchio and others 2014).

What technologies are being used to treat perchlorate?

Ex Situ Treatment

- Ion exchange using perchlorate-selective or nitrate-specific resins is a proven method for removal of perchlorate from drinking water, groundwater, and surface water (ITRC 2008).
- Ex situ bioremediation is being used to treat a large perchlorate plume in southern Nevada (NDEP 2017).
- Membrane technologies including electrodialysis and reverse osmosis have been used to remove perchlorate from groundwater, surface water

- and wastewater; however, these all require subsequent disposal of the perchlorate removed (EPA FFRRO 2005; ITRC 2008).
- Although standard granular activated carbon (GAC) does not efficiently remove perchlorate, the adsorptive capacity of GAC may be increased through the addition of a surfaceactive coating to produce a modified or tailored GAC. Tailored GAC has proven to be effective for treating perchlorate in water; however, it

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- produces a waste stream requiring management (Hou and others 2013; ITRC 2008).
- Laboratory-study results indicate that an electrically switched ion exchange system using a conductive carbon nanotube nanocomposite material could be used for the large-scale treatment of wastewater and drinking water. This approach would produce less secondary waste than conventional ion exchange processes (DoD SERDP 2011).
- A recent field study demonstrated the effective treatment of perchlorate-contaminated groundwater to below detection limits using a large-scale weak base anion resin ion exchange system. This system allows efficient and economical regeneration of the spent resin (DoD ESTCP 2012b).
- A fluidized bed biological reactor treatment train successfully treated low concentrations of perchlorate in groundwater to meet the California drinking water standards (6 μg/L) in a field study. The microbial process completely destroyed the perchlorate molecules, so no subsequent treatment or waste disposal was needed (DoD ESTCP 2009b).
- * Laboratory study results indicate that ultraviolet laser reduction can be used to decompose low levels of perchlorate (below 100 μg/L) in water. This technology is currently undergoing laboratory testing and has not yet been commercialized or used in full-scale systems (ITRC 2008). One laboratory study found that ultraviolet light and sulfite are able to degrade perchlorate when used together, but not when used alone (Vellanki and others 2013).

In Situ Treatment

- Enhanced in situ bioremediation using ubiquitous perchlorate-reducing microbes can be an effective method for degrading perchlorate in groundwater and soil, at a lower cost than ex situ methods (DoD SERDP 2002; ITRC 2008; Stroo and Ward 2008).
- A laboratory study found that adding acetate or hydrogen as electron donors can increase perchlorate removal efficiency in groundwater (Wang and others 2013).
- Field study demonstration results indicate that a horizontal flow treatment well system can effectively deliver electron donor and promote the in situ biological reduction of perchlorate in groundwater (DoD ESTCP 2009c).

- A field study evaluated the use of gaseous electron donor injection technology for the anaerobic biodegradation of perchlorate in vadose zone soil. Results showed an average perchlorate destruction of more than 90 percent within the targeted 10-foot radius of influence within five months (DoD ESTCP 2009d).
- * A field study evaluated the use of an emulsified oil biobarrier to enhance the in situ anaerobic biodegradation of perchlorate and chlorinated solvents in groundwater. Within 5 days of injection, perchlorate was degraded from an initial concentration range of 3,100 to 20,000 µg/L to below detection limits (less than 4 µg/L) in the injection and nearby monitoring wells (DoD SERDP 2008).
- A field study demonstrated that enhanced in situ bioremediation of perchlorate-impacted groundwater is effective using either an active or semi-passive approach. The active approach used on-going groundwater recirculation and delivery of an electron donor; perchlorate concentrations as high as 4,300 μg/L were reduced to less than 4 μg/L within 50 feet of the electron donor delivery/recharge well. The semi-passive approach involved periodic delivery of electron donor; perchlorate concentrations were reduced from levels over 800 μg/L to an average concentration of 3.4 μg/L (DoD ESTCP 2009a, 2012a).
- Laboratory and field studies have demonstrated the potential for using monitored natural attenuation to treat perchlorate in groundwater (DoD ESTCP 2010).
- * Several bench-scale tests have demonstrated the potential effectiveness of phytoremediation and constructed wetlands to treat perchlorate-contaminated media; limited field study demonstrations have been implemented (ITRC 2008). Recent laboratory study results indicate that the wetland plant, *Eichhornia crassipes*, may be an effective plant for constructing a wetland to remediate high levels of perchlorate in water based on its high tolerance and accumulation ability (He and others 2013).
- DoD's environmental research programs have funded many projects to research the remediation of perchlorate. For more information, see www.serdp-estcp.org/Featured-Initiatives/Cleanup-Initiatives/Perchlorate and www.serdp-estcp.org/Tools-and-Training/Environmental-Restoration/Perchlorate.

Where can I find more information about perchlorate?

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Where can I find more information about perchlorate? (continued)

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Technical Fact Sheet - Perchlorate

Where can I find more information about perchlorate? (continued)

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Additional information on perchlorate can be found at EPA's www.cluin.org/perchlorate.

Contact Information

If you have any questions or comments on this fact sheet, please contact: Mary Cooke, FFRRO, at cooke.maryt@epa.gov.



[SEQ CHAPTER \h \r 1]Internal Meeting/Briefing Request Form for Administrator Gina McCarthy

Today's Date: 15 October 2015

Requesting Office: OSWER

Title of the Meeting: Interim Roadmap for Addressing Perfluorinated Compounds (PFCs) under CERCLA

("PFC Roadmap") Briefing

Purpose: The Administrator has requested a briefing on the PFC Roadmap before its release.

Role of the Administrator: Informational Briefing

Background: There have been an increasing number of contaminated sites where perfluorinated compound (PFC) releases have been detected at levels of potential concern. PFCs are toxic chemicals that are extremely persistent in the environment. They have been used in a wide variety of industrial and commercial products, and have been identified in soil and groundwater at areas associated with fire training, metal plating facilities, airfields, aircraft hangars, and manufacturing facilities. To ensure national consistency and increase awareness of the need to address this class of contaminants in the environment, OSWER has developed the "Interim Roadmap for Addressing Perfluorinated Compounds (PFCs) under CERCLA ("PFC Roadmap")." The Roadmap compiles existing EPA policy and guidance that pertain to PFC releases.

Last possible date for the meeting: Charlotte Bertrand, FFRRO Acting Director, is unavailable the week of October 26th. November 3rd would be ideal.

Is the meeting urgent and if so, why?: While not urgent, the release of the Roadmap is highly anticipated by OSWER, ORD and the Regions. Its release was scheduled for the week of October 12, 2015.

Requested Time Length: 45 mins

EPA Staff (Required):
Mathy Stanislaus, OSWER
Barry Breen, OSWER
Nitin Natarajin, OSWER
Charlotte Bertrand, OSWER
Mary T Cooke, OSWER
James Woolford, OSWER
Mike Scozzafava, OSWER

NOTE: All OA Special Assistant's must be CC on all requests to the Administrator's Scheduling Office. All briefing material must be sent to [HYPERLINK "mailto:briefings@epa.gov"] 72 hours before the scheduled meeting. Failure to comply will result in the meeting being rescheduled at the Director of Scheduling and Advance's discretion.

Dana Stalcup, OSWER Linda Gaines, OSWER Josh Woodyard, OSWER Reggie Cheatham, OSWER Joel Beauvais, OP Betsy Behl, OW Elizabeth Southerland, OW Ken Kopocis, OW Laurence Libelo, OCSPP Jim Jones, OCSPP Lek Kadeli, ORD

EPA Staff (Optional):

External Participants: None

Teleconference Required?: No

Video Conference Required?: No

Point of Contact for the Meeting: Nick Hilosky, 202-566-1942; Mary Cooke 703-603-8712

NOTE: All OA Special Assistant's must be CC on all requests to the Administrator's Scheduling Office. All briefing material must be sent to [HYPERLINK "mailto:briefings@epa.gov"] 72 hours before the scheduled meeting. Failure to comply will result in the meeting being rescheduled at the Director of Scheduling and Advance's discretion.

Perchlorate and Drinking Water



Option Selection Briefing for the Administrator

January 14, 2010

Purpose of Meeting



- Background information
 - Regulatory determination
 - Regulation promulgation
- 2. Decide whether to regulate perchlorate in drinking water
- 3 Discuss schedule

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SDWA Regulatory Determination



- SDWA requires EPA to promulgate a drinking water regulation for a contaminant if the Administrator determines that:
 - the contaminant may have an adverse effect on the health of persons;
 - 2. the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and
 - 3. in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

(See slide 16 for information on how these criteria have been assessed)

 SDWA also requires EPA to take into consideration the effect contaminants have on subgroups at greater risk of health effects that comprise a meaningful portion of the general population

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1st Regulatory Determination Criteria: Health Effects



- Perchlorate interferes with the functioning of the thyroid gland by inhibiting iodide uptake.
 - Nitrate and isocyanates also inhibit iodide uptake (see slides 17-18)
- Iodide is an important component in synthesis of thyroid hormones which are critical for normal growth and development.
- Poor iodide uptake and subsequent impairment of thyroid function in pregnant and lactating women is linked to delayed development and decreased learning capability in infants and children with fetal and neonatal exposure.

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1st Regulatory Determination Criteria: Health Effects (cont.)

- The National Academies of Science (2005) recommended a reference dose (RfD) of 0.7 μ g/kg/day based on a small percentage change in iodide uptake in humans that were exposed to perchlorate for 2 weeks. The NAS stated that iodide uptake inhibition is not an adverse effect and that using a nonadverse effect is a conservative approach to perchlorate hazard assessment. A factor of 10 was applied to protect the most sensitive population, the fetuses of pregnant women who might have hypothyroidism or iodide deficiency.
- Recent CDC studies indicate the presence of perchlorate in the urine of all individuals tested at levels that are 10-fold lower than the RfD. These studies show an association between perchlorate exposure and thyroid hormone variations in adult women with lower than normal iodide levels. This effect has raised concerns since it was observed at doses lower than the RfD and in a potentially significant proportion of the population. CDC is repeating the analysis to affirm their findings.

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2nd Regulatory Determination Criteria: Levels of Public Health Concern

- (6)
- Different approaches to determine the Health Reference Level (HRL)
 - 10/08 Preliminary Determination HRL = 15 μg/L
 - Traditional adult (70 kg drinking 2 L/day) and dietary exposure data for pregnant women
 - * Physiologically Based PharmacoKinetic (PBPK) model estimated iodide uptake inhibition for other sensitive life stages at 15 μg/L (see slide 19)
 - PBPK model predicted iodide uptake inhibition consistent with the level NAS defined as a non adverse effect level in healthy adults
 - However, criticisms of the analysis have been raised, including the dose that infants receive at the HRL could be up to 5 times the reference dose
 - 8/09 Supplemental Request for Comment presented alternative HRLs based on exposure data for 13 life stages (see slide 20)
 - * Lowest alternative HRL = 2 μg/L for infants birth to 6 months
 - * Discussed criticisms of the 10/08 application of the PBPK model
 - * Requested cmt on limited use of PBPK (e.g., for sensitivity analysis)

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2nd Regulatory Determination Criteria (cont.): Frequency and Level of Occurrence



- 3,865 public water systems sampled the entry points to their distribution system under the Unregulated Contaminant Monitoring Rule (see slide 21)
- 160 systems found perchlorate in at least 1 sample
 - These 160 systems reported perchlorate in 637 of the 5,629 samples they collected
 - * Many of the entry points to these water system did not detect perchlorate
 - For entry points where perchlorate was detected, it was not necessarily found in all samples taken over time
- We estimate the frequency of water systems with drinking water at levels of concern from the UCMR data.

Potential Health Reference Level (μg/L)	% Systems with at Least 1 Detection >HRL Anywhere in System	
2	9%*	
4	4.1%	
15	0.8%	

^{*}Modeled value - the UCMR Method reporting limit was 4 µg/L.

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3rd Regulatory Determination Criteria: Opportunity for Health Risk Reduction



- We estimate the population served by systems with at least one perchlorate detection above a potential HRL
 - The middle column sums the population of the all the water systems with at least one detection, the right column adjusts the population to account for the entry points in these systems where perchlorate was not detected
- We estimate that 0.4 to 1.2 million infants, children and pregnant women are served by systems with perchlorate above their life stage-specific HRL.
 - Reducing perchlorate in drinking water may reduce this population's exposure to levels lower than the RfD (but will not eliminate exposure, see slides 22-23).

Potential Health Reference Level (μg/L)	Population Consuming Water Containing Perchlorate at Levels that Could Exceed the HRL		
	Upper-Bound Estimate	Adjusted Estimate	
2	34 M*	14 M*	
4	16.6 M	5.1 M	
15	2.0 M	0.9 M	

^{*}Modeled value - the UCMR Method reporting limit was 4 µg/L.

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SDWA Regulation Development



- For each contaminant the Administrator determines to regulate, SDWA requires EPA to:
 - Propose a regulation not later than 24 months after the determination. In the regulation, EPA must:
 - Establish a non-enforceable maximum contaminant level goal (MCLG)
 - * Determine the "feasible" level for the enforceable maximum contaminant level (MCL)
 - * Estimate the health risk reduction costs and benefits of alternative MCLs
 - * Determine if benefits justify the costs at the feasible level
 - * Determine if affordable compliance technologies are available to small systems
 - Promulgate a regulation within 18 months of proposal (may be extended by up to 9 months)

SDWA Section 1412(b)(1)-(6)

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Regulatory Promulgation Issues



- Feasibility and risk/risk tradeoffs
 - \circ Improved analytical methods can measure perchlorate at or above 0.6 $\mu g/L$
 - o Full scale field studies demonstrate ion exchange is a feasible treatment
 - However, perchlorate can form in hypochlorite used for disinfection
 - \star Massachusetts established a perchlorate standard of 2 µg/L to avoid risk/risk tradeoffs of a lower standard
- Cost/benefit considerations
 - Estimated costs of treatment range \$140 \$560 per year per household (see slide 24)
 - o However, cannot quantify health risk reduction benefits
 - Can predict population with avoided exposure to perchlorate, but not avoided hypothyroidism, neurodevelopmental or other adverse health effects.
- This would also be the next test of the small system variance policy
- Statute silent on whether EPA can reverse/withdraw a determination to regulate

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Option 1: Regulate Perchlorate * Rationale Deliberative Process / Ex. 5 Date Deliberative - Do Not Cite, Quote, Distribute Date Time!

Option 1: Regulate Perchlorate (cont.) * Considerations Deliberative Process / Ex. 5 Deal Deliberative - Do Not Gite Quote Distribute [DoteTime]

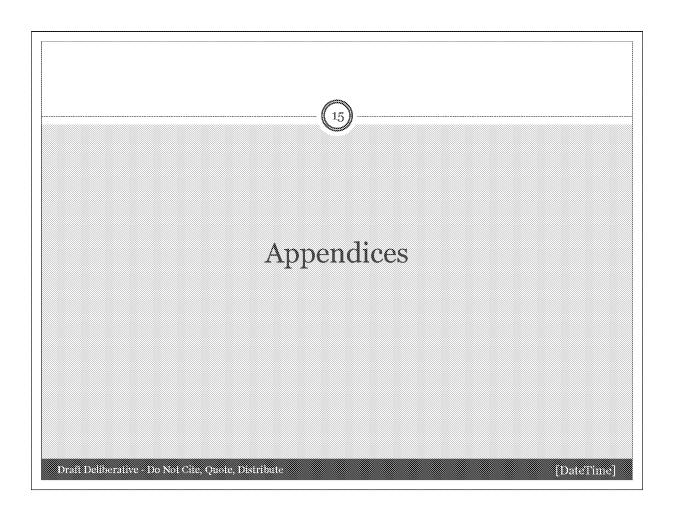
Option 2: Do not Regulate Perchlorate Rationale Deliberative Process / Ex. 5 * Considerations Deliberative Process / Ex. 5

Perchlorate Schedule



- Expedited schedule reflects high priority the Administrator and OW Assistant Administrator have placed on completing Regulatory Determination.
 - Final Agency Review: 3/22/10 3/26/10 (one week)
 - o OMB/interagency review: 4/19/10 5/18/10 (one month)
 - o Signature of final regulatory determination: 6/15/10
- * This expedited schedule does not include time to address new issues/scientific data that may arise.
- * If determination is to regulate perchlorate, then with a similarly expedited schedule, we estimate a proposed rule by June, 2011 and a final promulgation by June, 2012.

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Statutory Criteria and Information Considered for Past Regulatory Determinations

	Statutory Criteria	Information Considered During Evaluation	
1	The contaminant may have an adverse effect on the health of persons	Most recent Agency risk assessment (IRIS, OPP, OW), potential health effects, and Reference Dose (RfD) and/or cancer slope factor	
2	The contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern	 *Use health information to derive a health reference level (HRL) *HRL = ((RfD x Body weight)/Drinking Water Intake) x relative source contribution *Determine the relative source contribution (RSC) using dietary and other exposure data it available, however, the RSC is typically assumed to be 20% because data are not available. *Compare HRL to nationally representative drinking water occurrence data. *Primary source for drinking water occurrence data is the Unregulated Contaminant Monitoring Regulation (UCMR). Also use previous Unregulated Monitoring Contaminant Surveys. *If available, review supplemental information (e.g., USGS and State data) 	
3	In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems Consider variety of factors which include: Population exposure (typically based on drinking water occurrence data) For non-carcinogens, consider relative exposure from drinking water and other (i.e., RSC) Sensitive life stages National distribution of occurrence		

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Cumulative Effects of Iodide Uptake Inhibiting Contaminants



- Many compounds have adverse impacts on the thyroid (perchlorate, nitrate, isocyanate)
- They have the same mode of action as perchlorate
- Impact on the thyroid is mediated by iodide nutritional status
- Food is a more significant source of each of these compounds than water
 - Natural food constituent
 - Preservative added in manufacturing
 - o Contaminant taken up from soil or water
- Regulating perchlorate in water will have little effect on these other compounds
- Overall exposure to Thyroid-Inhibiting Compounds will remain largely unchanged

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OIG Scientific Analysis of Perchlorate



- On December 31, 2008 the EPA Office of Inspector General (OIG) released for comment a cumulative risk report for exposure to thyroid active compounds with a focus on perchlorate.
- Technical reviewers contracted by the OIG commented on a previous draft of the OIG report stated that the analysis and conclusions of the OIG draft report were outside the realm of available data.
- Recommendations in draft OIG report:
 - "A cumulative risk assessment approach is required to better characterize the risk to the public from a low total iodide uptake (TIU) during pregnancy and lactation." (thiocyanate, nitrate, perchlorate and lack of iodide)
 - O "Potentially lowering the perchlorate drinking water limit from 24.5 ppb to 6 ppb does not provide a meaningful opportunity to lower the public's risk. By contrast, addressing moderate and mild iodide deficiency occurring in about 29% of the U.S. pregnant and nursing population appears to be the most effective approach of increasing TIU to healthy levels during pregnancy and nursing, thereby reducing the frequency and severity of permanent mental deficits in children."

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PBPK Model



- * The FR notice stated that at the HRL of 15 ppb, the model shows iodide uptake inhibition for all subgroups that is comparable, and generally lower, to the inhibition at the NOEL (1.8%) selected by the NAS. Therefore, the notice concluded that the HRL is an appropriate level for other subpopulations.
- However, three of the four peer reviewers who were asked to comment on the application of the PBPK modeling in the FRN were critical of the analysis and the conclusions. In addition, several environmental groups, and EPA's Childrens' Health Protection Advisory Panel, issued public statements of concern regarding the analysis.
- Specifically, there are several potential technical problems that have been cited:
 - Populations other than the pregnant woman have been identified as potentially more vulnerable.
 - If the intent was that the use of the PBPK model accounted for the 10-fold UF, this may not be a valid assumption. For example, the model indicates that the fetus is already 7-fold more sensitive than an adult without taking iodine deficiency within the population into account.

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Alternative HRLs (μ g/L) – August, 2009

Life Stage	Mean Ingestion Rate HRL	90 th Percentile Ingestion Rate HRL	95 th Percentile Ingestion Rate HRL	
Birth to < 1 month	3	2*	2*	
1 to < 3 months	3	2*	1*	
3 to < 6 months	5	3	2	
Birth to < 6 months	4	2	2	
6 to < 12 months	8	4	3	
1 to < 2 years	11	6	4	
2 to < 3 years	12	6	5	
3 to < 6 years	18	9	6	
6 to < 11 years	29	14	11	
11 to < 16 years	45	23	17	
16 to < 18 years	47	23	18	
18 to < 21 years	43	19	16	
Pregnant women	31	13	10	

*The sample sizes for the estimates of ingestion rates for these life stages do not meet minimum data requirements.

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Perchlorate in Drinking Water



- Data source: EPA's Unregulated Contaminant Monitoring Regulation (UCMR)
- 34,331 samples were collected from 3,865 public water systems between 2001 and 2005
- Surface water systems collected quarterly samples, ground water systems collected semiannual samples
- Findings:
 - \circ Percent **samples** with perchlorate at, or above, the minimum reporting level (MRL = 4 μ g/L): 1.9% (637 out of 34,331 samples)
 - Percent systems reporting perchlorate at, or above, the MRL in at least one sample: 4.1% (160 out of 3,865 systems)
 - Perchlorate concentration among systems reporting:
 - ο Average: 9.85 μg/L
 - ο Median: 6.40 μg/L
 - Percent estimated population exposed to perchlorate in these systems: 2.3% 7.3%
 (5.1 M 16.6 M out of 226 M people)
 - * Locations of these systems: 26 States, 2 territories

Lateline

Perchlorate in Food



- Perchlorate has been reported in FDA's Total Diet Study (TDS) in 74% of food and beverages.
- FDA estimated mean dietary intakes of perchlorate for 14 different age and gender groups
 - Infants and children have the highest average intake on a body-weight basis
 - st 2 year olds mean dietary intake of perchlorate is as much as 50% of the RfD
- EPA and CDC evaluated NHANES biomonitoring data against UCMR
 - Estimated pregnant women consume as much as 38% of the RfD in their diet

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Perchlorate Exposure



- CDC collects biomonitoring data for ages 6 and older.
- For survey years 2001-2002, National Health and Nutrition Examination Survey (NHANES) measured urinary perchlorate levels.
- Low perchlorate exposure is widespread in the U.S. population but generally is below the RfD.
- * "Among women with lower levels of iodine in their urine, perchlorate exposure . . . was associated with small- to medium-size changes in thyroid hormone levels."

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Preliminary Cost Estimates – Ion Exchange



System Size (population served)	Household Costs (per year)
25-500	\$557
501-3,300	\$196
3,301-10,000	\$175
50,000	\$148
280,000	\$140

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Dateline

October 2008 Preliminary Determination



- st Perchlorate Health Reference Level set at 15 $\mu g/L$ based on pregnant women and fetus
 - Used Physiologically Based Pharmacokinetic (PBPK) modeling to evaluate potential impacts on infants and children at this level
 - Concluded that perchlorate does not occur at a frequency and level of health concern to warrant a NPDWR despite data showing infants and children exposed above the RfD
 - NPDWR would not present "a meaningful opportunity for health risk reduction for persons served by public water systems"

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October 2008 Summary of Comments



- Comment letter tally
 - Total: ~ 32,491
 - o Unique: ~ 1,106 (3%)
 - 7 apparent mass-mailing campaigns (environmental): ~ 31,385
 (97%)
- Comment letters by stakeholder category
 - o Environmental/public health groups (6)
 - o States (8: AZ, CA, MA, MD, NJ, NM, OR, WA)
 - Trade associations/groups (8)
 - Other informative comment letters
 - * Children's Health Protection Advisory Committee
 - * Science Advisory Board

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[Date Fine]

January 2009 Announcement



- EPA announced we would seek further review by the National Academies of Science prior to issuing a final regulatory determination for perchlorate
- OW Issued an interim health advisory (HA = 15 μ g/L) as guidance to state and local officials
- * OSWER revised its preliminary remediation goal (PRG) under CERCLA (PRG = 15 μ g/L)

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August 2009 Supplemental Notice



- Notice sought input on additional ways to analyze data:
 - Re-evaluation of perchlorate exposure to all sensitive life stages, including infants, children and the fetuses of pregnant women
 - Ways to use the PBPK modeling analysis to inform the regulatory determination
 - Use of a Bayesian model to estimate the number of public water systems, and populations served by such systems, at various perchlorate concentrations (UCMR 1 MRL = 4 μg/L)

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2008 & 2009 Commenter Positions



Regulate

- >38,000 individuals were a part of organized comment campaigns
- Children's Health Protection Advisory Committee
- Clean Water Action
- Earth Justice
- o Environmental Defense Fund
- Environmental Working Group
- Food and Water Watch
- Metropolitan Water District of Southern California
- Natural Resources Defense Council
- o 9 States: AZ, CA, MA, MD, MN, NJ, NM, OR, WA

Do not regulate

- American Water Works Association
- "California Agricultural Industry" (13 groups)
- National Association of State Departments of Agriculture
- National Rural Water Association
- o Perchlorate Study Group
- Association of State Drinking Water Administrators (acknowledged that some states favored regulation)
- o 2 States: NV, SD

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Dateline

August 2009 Summary of Comments



Comment letter tally

- Total: ~ 6,159
- o Unique: ~ 217 (3.5%)
- \circ 2 apparent mass-mailing campaigns (environmental): ~ 5,942 (96.5%)

Comment letters by stakeholder category

- o Environmental/public health groups (4)
- o States (5: MA, MN, NJ, NV, SD)
- o Trade associations/groups (20)
- Other informative comment letters: Department of Defense

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August 2009 Commenter Positions – Which HRL?



- Trade associations/groups
 - O Association of State Drinking Water Administrators: 4-15 μg/L
 - O American Water Works Association: 15 μg/L
- States
 - O MA: 2 μg/L
 - \circ MN: 1-3 µg/L
 - O NJ: < 15 μg/L
 - O NV: 15 μg/L
 - O SD: 15 μg/L
- Environmental/public health groups
 - O Clean Water Action: 1 μg/L
 - $\circ\,$ Environmental Working Group, Natural Resources Defense Council: < 1 $\mu g/L$

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August 2009 Commenter Positions – Use of Physiologically-based Pharmacokinetic Model



- Modeling approach used to predict radioactive iodide uptake inhibition in the thyroid for various life stages and drinking water concentrations
- Trade associations/groups
 - o Association of California Water Agencies: Use requires justification
 - o Association of Metropolitan Water Agencies: Recommends NAS review
 - o American Water Works Association: Model outdated
 - o Perchlorate Study Group: Revise model and use results
- States
 - o MA: Do not use
 - o NJ: Use with caution
 - o NV: Revise and use results
- Environmental/public health groups
 - o Environmental Working Group: Use with significant limitations
 - o Natural Resources Defense Council: Use to evaluate life stage sensitivity
- Other
 - o Department of Defense: Needs revision

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August 2009 Commenter Positions – Use of Bayesian Analysis



- * Modeling approach used to predict perchlorate concentrations < 4 μg/L
- Trade associations/groups
 - o Association of California Water Agencies: Not useful, universal contamination
 - Association of Metropolitan Water Agencies: No comment; however, perchlorate occurrence has dropped and levels are not evenly distributed
 - American Water Works Association: Analysis inappropriate since UCMR 1 data for perchlorate is outdated
 - Association of State Drinking Water Administrators
 - * Conduct analysis; however, some states do not have significant/any occurrence
 - * UCMR 1 perchlorate data is outdated
 - o Perchlorate Study Group: UCMR 1 perchlorate data is outdated
- States
 - o MA: Reasonable approach however data may not reflect true national occurrence
 - NJ: Supports use
 - o NV: UCMR i perchlorate data is outdated

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Datelime

Message

From: Skane, Elizabeth [Skane.Elizabeth@epa.gov]

Sent: 6/18/2020 1:23:26 PM

To: Skane, Elizabeth [Skane.Elizabeth@epa.gov]

Subject: EPA Hill notification: EPA Issues Final Action for Perchlorate in Drinking Water

Good Morning, please see the press release below regarding EPA action on perchlorate in drinking water. Please let me know if you have any questions.

Best,

Elizabeth

Elizabeth Skane * 202.564.5696

US Environmental Protection Agency Office of Congressional Affairs WJC North 34435

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EPA Issues Final Action for Perchlorate in Drinking Water

WASHINGTON (June 18, 2020) — Today, the U.S. Environmental Protection Agency (EPA) issued a final action regarding the regulation of perchlorate under the Safe Drinking Water Act (SDWA). Considering the best available science and the proactive steps that EPA, states and public water systems have taken to reduce perchlorate levels, the agency has determined that perchlorate does not meet the criteria for regulation as a drinking water contaminant under the SDWA. Therefore, the agency is withdrawing the 2011 regulatory determination and is making a final determination to not issue a national regulation for perchlorate at this time.

"Today's decision is built on science and local success stories and fulfills President Trump's promise to pare back burdensome 'one-size-fits-all' overregulation for the American people," said EPA Administrator Andrew Wheeler. "State and local water systems are effectively and efficiently managing levels of perchlorate. Our state partners deserve credit for their leadership on protecting public health in their communities, not unnecessary federal intervention."

Reductions of perchlorate contamination have resulted from actions taken by EPA, states and public water systems. The main factors contributing to the decrease in perchlorate levels include:

- Drinking water regulations for perchlorate in Massachusetts and California.
- Federal and state remediation activities at perchlorate contaminated sites, particularly the ongoing remediation efforts in the state of Nevada to address perchlorate contamination in groundwater adjacent to the lower Colorado River upstream of Lake Mead.
- Improved procedures for storage and handling of hypochlorite solutions used as drinking water disinfectants.

EPA also performed a new health impact analysis based on recommendations from the Science Advisory Board. The new analysis shows that the concentrations at which perchlorate may present a public health concern are higher than the concentrations considered in the 2011 regulatory determination.

The updated occurrence information and the new health impact analysis are the best available information. Based on this updated data and analysis, EPA is making a final determination that perchlorate is not found in drinking water with a frequency and at levels of public health concern to support a meaningful opportunity for health risk reduction through a national perchlorate drinking water regulation.

EPA will continue to work with state partners to provide safe drinking water to all Americans. To assist states and drinking water systems interested in reducing

perchlorate concentrations, EPA is providing steps that water systems can take to mitigate the contaminant if and where it occurs.

Background

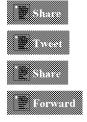
Perchlorate is commonly used in solid rocket propellants, munitions, fireworks, and airbag initiators for vehicles, matches, and signal flares. Perchlorate may occur naturally, particularly in arid regions such as the southwestern U.S., and can be found as a byproduct in hypochlorite solutions used for treating drinking water and nitrate salts used to produce fertilizers, explosives, and other products.

For more information visit: https://www.epa.gov/sdwa/perchlorate-drinking-water

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